

TITLE 3. DEPARTMENT OF PESTICIDE REGULATION
Changes to Efficacy Data Requirements for Pesticide Products
DPR Regulation No. 05-002

NOTICE OF PROPOSED REGULATORY ACTION

The Department of Pesticide Regulation (DPR) proposes to amend sections 6186, 6200, and 6222 of Title 3, California Code of Regulations (3 CCR). The proposed regulatory action pertains to efficacy data requirements for pesticide products.

SUBMITTAL OF COMMENTS

Any interested person may present comments in writing about the proposed action to the agency contact person named below. Written comments must be received no later than 5:00 p.m. on August 1, 2005. Comments regarding this proposed action may also be submitted via e-mail <dpr05002@cdpr.ca.gov>, or by facsimile (FAX) transmission at (916) 324-5872.

A public hearing is not scheduled; however, a public hearing will be scheduled if any interested person submits a written request for a public hearing to DPR no later than 15 days prior to the close of the written comment period.¹

EFFECT ON SMALL BUSINESS

DPR has determined that the proposed regulatory action may affect certain types of small businesses.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Food and Agricultural Code (FAC) section 12753 defines a "pesticide" as: (1) any spray adjuvant; and (2) any substance, or mixture of substances, that is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest, as defined in FAC section 12754.5, that may infest or be detrimental to vegetation, man, animals, or households, or be present in any agricultural or nonagricultural environment. FAC section 11501 requires DPR "to assure users that pesticides are properly labeled and are appropriate for the use designated by the label." FAC section 12824 requires DPR to endeavor to eliminate from use in California any pesticide not beneficial for the purposes for which it is sold. FAC section 12825 authorizes DPR to cancel the registration of any pesticide "that is of little or no value for the purpose for which it is intended."

Currently, an applicant for registration of a new pesticide product or amendment to the labeling of a currently registered pesticide product is required by 3 CCR section 6186 to submit efficacy data supporting each efficacy claim on the product label. DPR reviews the efficacy data prior to registration of the pesticide product or accepting the amended label.

¹ If you have special accommodation or language needs, please include this in your request for a public hearing. TTY/TTD speech-to-speech users may dial 7-1-1 for the California Relay Service.

DPR first opened the subject of efficacy data requirements for pesticide products to the public for comment in 1996. DPR held workshops throughout the State and received a number of written comments. In 1997, based upon the comments received at the workshops, DPR proposed amendments to sections 6186, 6200, and 6222. DPR received numerous comments in response to the proposed regulation change. In response to comments opposing the regulatory changes, DPR withdrew its proposal.

As a part of a pesticide product registration reform initiative, DPR is once again opening up the subject of efficacy data requirements for pesticide products in the form of a proposed regulatory change for public comment.

The U.S. Environmental Protection Agency (U.S. EPA) requires that each registrant ensure through testing that a pesticide product will be efficacious when used in accordance with label directions and commonly accepted pest control practices. However, U.S. EPA only requires the submission of efficacy data to support the registration or amendment of pesticide products that bear claims to control pest organisms that pose a threat to human health. Such pests include: (a) microorganisms which are infectious to man in any area of the inanimate environment, (b) vertebrates (e.g., rodents, birds, bats, dogs, and skunks) that may directly or indirectly transmit diseases to or injure humans, and (c) insects that carry human diseases (e.g., mosquitoes, ticks, etc.). On a case-by-case basis, U.S. EPA may require the submission of efficacy data to substantiate other types of efficacy claims. Current efficacy data submission requirements in California exceed those of the U.S. EPA and any other state.

DPR proposes to amend sections 3 CCR sections 6186, 6200, and 6222. Proposed section 6186 requires an applicant for registration of a new pesticide product or an amendment to the labeling of a currently registered pesticide product to submit efficacy data only for efficacy claims that are determined by the Director to be significantly different (as defined by the regulation) from one or more currently registered pesticide product labels. The proposed regulation change would also authorize the Director, at any time, to require the submission of efficacy data for any label claim on a registered pesticide product or a product proposed for registration.

In order to fully implement the changes in efficacy data requirements, DPR needs to make corresponding amendments to sections 6200 and 6222. Section 6200 authorizes DPR to grant conditional registrations as long as "preliminary efficacy data indicating the product is effective for the proposed use" have been submitted. The proposed amendment to section 6200 clarifies that if an applicant is not required to submit efficacy data pursuant to section 6186 for one or more efficacy claims, then preliminary efficacy data are not required for those label claim(s) to obtain a conditional registration. The proposed amendment to section 6222 clarifies that under the reevaluation process, DPR retains its authority to require the submission of efficacy data on any pesticide product.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DPR has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. DPR has also

determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

DPR anticipates that there will be no fiscal impact to these agencies because the proposed regulatory action makes no change to any existing regulations that are enforced by any local agency.

COSTS OR SAVINGS TO STATE AGENCIES

DPR has determined that no net savings or increased costs to DPR will result from the proposed regulatory action. The proposed regulatory change may reduce DPR's workload in the area of efficacy data review; however, due to personnel cuts and DPR's backlog of registration applications, any savings from the proposed regulatory change will be put towards reducing the backlog and speeding up the pesticide registration process. No positions will be eliminated. DPR has determined that no increased costs or savings to any other state agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

DPR has determined that no costs or savings in federal funding to the state will result from the proposed action.

EFFECT ON HOUSING COSTS

DPR has made an initial determination that the proposed action will have no effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE IMPACT DIRECTLY AFFECTING BUSINESSES

DPR has made an initial determination that the adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with business in other states.

COST IMPACT ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

DPR has made an initial determination that the adoption of this regulation may result in a cost savings to private persons or businesses that register pesticide products for sale in California; however, the cost savings is not likely to be significant. U.S. EPA requires all applicants to conduct efficacy studies; therefore, the savings to the regulated community would be the cost of submitting the studies to DPR for review. The proposed regulatory action may result in a cost impact to private persons or businesses that conduct efficacy studies for pesticide companies. These companies may experience a loss of business for efficacy studies to be conducted in California. The agency is not aware of any cost impacts to other representative private persons or business from the proposed regulatory action.

IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

DPR has determined it is unlikely that the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

CONSIDERATION OF ALTERNATIVES

DPR must determine that no reasonable alternative considered by the agency, or that has otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses.

AUTHORITY

This regulatory action is taken pursuant to the authority vested by Food and Agricultural Code sections 11456 and 12781.

REFERENCE

This regulatory action implements, interprets, or makes specific Food and Agricultural Code sections 11501, 12824, 12825, 12825.5, 12826, 12827, and 12854.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

DPR has prepared an Initial Statement of Reasons and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulations may be obtained from the agency contact person named in this notice. The information upon which DPR relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After the close of the comment period, DPR may make the regulations permanent if they remain substantially the same as described in the Informative Digest. If DPR does make substantial changes to the regulations, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. DPR will accept written comments only on any changes for 15 days after the modified text is made available.

AGENCY CONTACT

Written comments about the proposed regulatory action; requests for a copy of the Initial Statement of Reasons; the proposed text of the regulation; and a public hearing; inquiries regarding the rulemaking file; or questions on the substance of the proposed regulatory action may be directed to:

Ann Prichard, Sr. Environmental Research Scientist
Department of Pesticide Regulation
Pesticide Registration Branch
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015
(916) 324-3931

Note: In the event the contact person is unavailable, inquiries should be directed to the following backup contact person at the same address as above.

Linda Irokawa-Otani, Regulations Coordinator
Office of Legislation and Regulations
(916) 445-3991

This Notice of Proposed Action, the Initial Statement of Reasons, and the proposed text of the regulation are also available on DPR's Internet Home Page <<http://www.cdpr.ca.gov>>.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9(a) may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on DPR's Internet Home Page and accessed at <<http://www.cdpr.ca.gov>>.

DEPARTMENT OF PESTICIDE REGULATION

Director

Date